

In the Claims:

Please add Claims 2-44, such that the Claims are as set forth below.

1. (Original) A device for determining the concentration of an analyte in a biological fluid from a patient, comprising:

a piercing member adapted to pierce and retract from a site on the patient to cause the fluid to flow therefrom;

a sensor positioned adjacent to the site on the patient and adapted to receive the fluid flowing from the site to generate an electrical signal indicative of the concentration of the analyte in the fluid, the sensor comprising a working electrode comprising an analyte-responsive enzyme and a redox mediator, and a counter electrode, wherein the working and counter electrodes are positioned to contact a sample in a measurement zone having a volume of less than about 1 μ l; and

an analyte monitor operatively connected to the sensor and adapted to measure the signal generated by the sensor.

2. (New) A device for determining a concentration of an analyte in a fluid from a site on a subject, comprising:

a piercing member sufficient to pierce the site such that the fluid flows therefrom;

a sensor comprising a working electrode, which comprises at least one agent sufficient for transferring electrons between the electrode and the analyte, a counter electrode, and a measurement zone having a volume of less than about 1 μ l for receiving a sample of the fluid, each of the working electrode and the counter electrode operably associated with the measurement zone, the sensor sufficient to generate a signal indicative of the concentration of the analyte in the sample; and

an analyzer operatively associated with the sensor, the analyzer sufficient to measure the signal from the sensor.

3. (New) The device of claim 2, wherein the piercing member is a lancet.

4. (New) The device of claim 2, wherein the at least one agent comprises a redox mediator.

5. (New) The device of claim 2, wherein the at least one agent comprises a redox mediator and an enzyme.

6. (New) The device of claim 5, wherein the enzyme is selected from a group consisting of a lactase oxidase, a glucose oxidase, and a glucose dehydrogenase.

7. (New) The device of claim 2, wherein the volume of the measurement zone is less than about 0.5 μl .

8. (New) The device of claim 2, wherein the sensor comprises a strip.

9. (New) The device of claim 2, wherein the working electrode is on a first substrate and the counter electrode is on a second substrate.

10. (New) The device of claim 2, wherein the sensor further comprises a third electrode.

11. (New) The device of claim 2, the sensor being such that the signal generated by the sensor in electrolysis of a buffer solution having a 10 mM concentration of the analyte is at least about nine times greater than the signal generated by the sensor in electrolysis of the buffer solution absent the analyte.

12. (New) The device of claim 2, further comprising a sorbent material for transporting the fluid from the site to the sensor.

13. (New) The device of claim 12, wherein at least a portion of the sorbent material is disposed in the measurement zone.

14. (New) The device of claim 2, further comprising means for transporting the fluid from the site to the sensor.

15. (New) The device of claim 14, wherein the means for transporting comprises vacuum-producing means.

16. (New) The device of claim 15, wherein the vacuum-producing means is a vacuum pump.

17. (New) The device of claim 14, wherein the means for transporting comprises at least one of pressure application, vacuum creation, capillary action, and wicking action.

18. (New) The device of claim 2, wherein the analyzer comprises an amperometric analyzer.

19. (New) The device of claim 2, wherein the analyzer comprises a coulometric analyzer.

20. (New) The device of claim 2, wherein the fluid is selected from the group consisting of blood, interstitial fluid, dermal fluid, sweat, and tears.

21. (New) The device of claim 2, wherein the analyte is selected from the group consisting of lactate and glucose.

22. (New) The device of claim 2, wherein the piercing member and the sensor form an integrated unit.

23. (New) The device of claim 22, wherein the sensor is detachable from the integrated unit.

24. (New) The device of claim 2, wherein the piercing member, the sensor, and the analyzer comprise integrated components of a single device.

25. (New) A method for determining the concentration of an analyte in a fluid from a site on a subject, the method comprising:

providing a piercing member, a sensor for generating a signal, and an analyzer for measuring the signal, wherein the sensor comprises a working electrode, which comprises at least one agent sufficient for transferring electrons between the electrode and the analyte, a counter electrode, and a measurement zone having a volume of less than about 1 μ l, each of the working electrode and the counter electrode operably associated with the measurement zone;

piercing the site via the piercing member such that a sample of the fluid flows from the site to the measurement zone;

generating a signal indicative of the concentration of the analyte in the sample of the fluid in the measurement zone via the sensor; and

measuring the signal via the analyzer.

26. (New) The method of claim 25, wherein the piercing member comprises a lancet.

27. (New) The device of claim 25, wherein the at least one agent comprises a redox mediator.

28. (New) The device of claim 25, wherein the at least one agent comprises a redox mediator and an enzyme.

29. (New) The device of claim 25, wherein the enzyme is selected from a group consisting of a lactase oxidase, a glucose oxidase, and a glucose dehydrogenase.

30. (New) The method of claim 25, wherein the volume of the measurement zone is less than about 0.5 μ l.

31. (New) The method of claim 25, wherein the working electrode is on a first substrate and the counter electrode is on a second substrate.

32. (New) The method of claim 25, wherein the sensor further comprises a third electrode.

33. (New) The method of claim 25, the sensor being such that the signal generated by the sensor in electrolysis of a buffer solution having a 10 mM concentration of the analyte is at least about nine times greater than the signal generated by the sensor in electrolysis of the buffer solution absent the analyte.

34. (New) The method of claim 25, further comprising transporting the fluid from the site to the measurement zone via a sorbent material.

35. (New) The method of claim 34, wherein at least a portion of the sorbent material is disposed in the measurement zone.

36. (New) The method of claim 25, further comprising, before said measuring, providing a vacuum at or around the site.

37. (New) The method of claim 25, further comprising transporting the fluid from the site to the measurement zone via at least one of vacuum, pressure, capillary action, and wicking action.

38. (New) The method of claim 25, wherein said measuring comprises amperometrically measuring.

39. (New) The method of claim 25, wherein said measuring comprises coulometrically measuring.

40. (New) The method of claim 25, wherein the fluid is selected from the group consisting of blood, interstitial fluid, dermal fluid, sweat, and tears.

41. (New) The method of claim 25, wherein the analyte is selected from the group consisting of lactate and glucose.

42. (New) The method of claim 25, wherein the site is located on an arm of the subject.

43. (New) The method of claim 25, wherein the piercing member and the sensor form an integrated unit.

44. (New) The method of claim 25, wherein the piercing member, the sensor, and the analyzer comprise integrated components of a single device.